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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,554	10/24/2003	Yasuyuki Kawashima	11333/29	1129

7590 04/05/2007
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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/692,554	KAWASHIMA ET AL.	
	Examiner	Art Unit	
	Natalia Levkovich	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks filed 01/17/2007 have been acknowledged by the Examiner.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

3. The amended claims 1-14 and the newly added claim 25 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 10 and 25 recite the sample preparation unit 'configured for preparing a measured sample by diluting the sample ...with an acidic solution'. Claim 25 also recites the pipette 'configured for suctioning the urine sample'. It is unclear what structural features of the above recited elements are intended by the Applicant to provide for the recited functionality.

Claim Rejections - 35 USC § 102

4. Claims 1-14 and 25 are rejected under 35 U.S.C. 102(b) as anticipated by Chupp et al. (US 5631165).

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With respect to claims 1, 10 and 25, Chupp discloses an automated analyzer for “distinguishing and differentiating cells in a sample”. The device comprises, as shown in Figures 3- 5, a sample processing area 110 [‘sample preparation unit’ – Ex.], aspiration probe 156 [‘pipette’ – Ex.] and “probe wash and dry unit” (not indexed). The system also includes “a dilution syringe coupled to the tubing network 182”, flow cells / impedance transducers 170, 174, 178 [‘detection units’ – Ex.] and a controller (Col. 7, lines 20-30).

In reference to claim 7, the impedance transducer 174 “performs impedance-based cell counting and sizing (Col. 39, lines 35 plus). “The data station 68 of the cell analysis system 60 has memories and other devices which apply algorithms for various cellular analyses. These algorithms are used to analyze clusters of data points generated by the analysis module 64 to yield information of clinical relevance. The disclosed integrated hematology/immunology instrument provides a single platform on which such software may be implemented, thereby providing an instrument that not only automates hematology and immunology sample processing and measurement, but also automates data analysis” (Col. 45, lines 55-60).

Referring to claim 14, Chupp teaches urine samples in column 10, line 47.

Regarding claims, 1-14 and 25, as was noted previously, the acidic solution (as well as the sample) is not positively claimed to be considered a part of the invention, and, therefore, is not accorded any patentable weight.

Response to Arguments

5. Applicant's arguments dated filed 01/17/2007 have been fully considered but they are not persuasive.

Applicant argues that the 35 U.S.C. 112, second paragraph, rejection is improper because 'Applicant may use functional language' and because 'a claim may not be rejected solely because of the type of language used to define the subject matter'. Examiner absolutely agrees with this statement..

Applicant, certainly, can use functional language in the apparatus claims provided that the structure of the apparatus is defined clearly, which is not the case, with respect to the instant claims (see the discussion above). Examiner also notes that the 35 U.S.C. 112, second paragraph, rejection was accompanied by the art rejection.

Applicant argues that Chupp et al. 'contains no teaching or suggestion of an 'acidic solution' as required by... claims 1 and 10". Examiner disagrees. As was noted earlier, the acidic solution is not positively claimed to be considered a part of the invention, and, therefore, is not accorded any patentable weight. Additionally, the device of Chupp is capable of providing the use acidic solutions for sample preparation. Moreover, Chupp does disclose the use of sulfonic acids as buffers (see, for example, the "Fast Lyse Multipurpose Reagent System" section).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jill Warden
Supervisory Patent Examiner
Technology Center 1700